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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,745	08/26/1999	MARIA ALEXANDRA GLUCKSMANN	5800-8A	6988
30405	7590	06/17/2005	EXAMINER	
MILLENNIUM PHARMACEUTICALS, INC.			TURNER, SHARON L	
40 Landsdowne Street			ART UNIT	
CAMBRIDGE, MA 02139			PAPER NUMBER	
			1647	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/383,745

Applicant(s)

GLUCKSMANN ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,34-37,39-42,44-47 and 49-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,34-37,39-42,44-47 and 49-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

1. The Examiner of U.S. Patent application SN 09/383,745 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1647.
2. The amendment filed 2-8-05 has been entered into the record and has been fully considered.
3. Claims 32, 34-37, 39-42, 44-47 and 49-59 are pending.
4. The Examiner notes the Decision of 7-24-04 in which the rejections under 35 USC § 101, 112, first paragraph, (enablement and written description), were vacated and rejection under 35 USC 102(e) was instituted. Reinstatement of the original grounds of rejection (under 35 USC § 101, 112, first paragraph, (enablement and written description)), is not inconsistent where no previous decision was rendered by the Board.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 32, 34-37, 39-42, 44-47 and 49-59 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, asserted utility or a well established utility.

Rejection is reinstated for the same reasons of record as extensively set forth in the prosecution history. In summary and with respect to the newly amended claims now directed to "an antibody which binds the polypeptide", "the antibody to modulate the

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activity of the polypeptide,” and “a cell which naturally expresses the polypeptide”, the specification remains deficient in defining specific and substantial utility. No specific or substantial function or activity of the peptide is supplied via the specification or recognized prior art and therefore the function and significance of the polypeptide is unknown. Further, no actual antibody is provided that is evidenced to bind and inhibit any activity, nor is there any evidence of a suitable assay for measuring the supposed modulation (of such peptide activity) within a cell that naturally expresses the polypeptide, specifically in brain, spleen, lung, kidney (disclosed but no longer claimed), skeletal muscle, liver and heart.

The specification contemplates the use of the disclosed polynucleotides, polypeptides, antibodies, vectors and host cells in various molecular biology techniques as detailed throughout the specification and summarized at pp. 3-5 noting particular use as reagents or targets in receptor assays applicable to treatment and diagnosis of G-protein coupled receptor (GPCR)-mediated disorders, to identify agonists, antagonists and modulators of expression, to make antibodies that selectively bind, methods of screening for compounds that modulate activity, including to treat related conditions and for diagnostic assays via determining presence. Pages 7-9 describe briefly Receptor function/signal pathway/ “signaling pathway” for G-protein coupled receptors in general for example noting that GPCR receptors function via various signaling mechanisms including mobilization of intracellular calcium, phosphatidylinositol pathways, adenylate cyclase, and polarization of the cell membrane amongst others. The specification p. 8 and notes that the 14926 protein is expressed in brain tissues. The specification also

denotes an extensive laundry list of disease contemplated as being treatable via the noted reagents and experimentation, see in particular pp. 27-34.

Such utilities and disclosure are neither specific nor substantial because the uses merely rely on the inherent properties of any nucleic acid to hybridize (bind) and encode, any polypeptide to bind or stimulate antibodies, and for any broad class of such molecular reagents (G-protein coupled receptors) to be used in research experimentation for detection, binding and competition assays amongst others. Accordingly the noted polypeptides merely constitute research reagents for further experimentation to discover their "real-world" use and significance. What is missing is the instructive or detailed analysis of the relationship of the 14926 peptide to any particular G-protein coupled receptor function, its significance with respect to any single effect, disease association, treatment paradigm or other significance that places the artisan in possession of a completed invention. In contrast, the teachings of the specification merely assert because of the proteins classification within the context of the broad class of G-protein coupled receptors in general, that the peptide provides patentable utility. Yet, such is not the case without the specific association that differentiates this G-protein coupled receptor from any one of its other family members either via similarity or difference, that is sufficient to attach functional significance and reasonably prescribed use. Such is not provided without these specifics because G-protein coupled receptor functions differ from each other significantly in use, effect and function.

For example, G-protein coupled receptors are inclusive of multiple distinct

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classes of receptors including Adrenoceptors, Angiotensin receptors, Calcitonin receptors, dopamine receptors, Gonadotrophin-releasing factor receptors amongst others as detailed in Stadel et al., TIPS 1997, of record. Each of these GPCR's bind a different ligand, mediate different signal transduction events in different cells and are related to different functions, effects and relate to different diseases as well as different disease states. Clearly identification of any new receptor fails to distinguish amongst the large number of members any similarity or difference in function, effect or use in relation to any other. GPCR homology does allow predictable comparison, whereby the artisan could conclude by mere placement of any peptide within the broad class of GPCR's which functions, effects, significance or use that peptide may have. Only upon disclosure of these specifics is the artisan provided a complete and useable invention. Accordingly, the specification fails to delineate a specific and substantial asserted utility.

The recited uses also do not constitute a well-established utility because the disclosed sequences are noted to be novel and are not noted to share particular structure, function, effect or significance with respect to any particular disease, diagnostic, prognostic or other patentable use. As previously noted, GPCR function and significance are unpredictable properties. This is further recognized by Skolnick et al., Trends in Biotech., 18(1):34-39, 2000 and Bork P., Genome Research 10:398-400, 2000. These references establish that the skilled artisan is well aware that there is an unpredictable nature in the ability of encoding nucleic or amino acids to predict structural and functional activities for any particular protein or protein family. As noted in each reference, even when highly homologous and conserved residues are known,

only experimental research can confirm the artisan's best guess. For example, Skolnick, see in particular abstract and Box 2, denote limitations in extrapolations amongst highly homologous families where even a single amino acid exchange may alter protein function and effect. Thus, the mere assignment of instant SEQ ID NO's 1 and 2 as encoding a GPCR protein, fails to provide sufficient information to provide specific and substantial or well established utility within the context of 35 USC 101. Therefore, rejection is maintained.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 32, 34-37, 39-42, 44-47 and 49-59 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In addition to the aforementioned, the following defects are noted with respect to enablement of the invention as instantly claimed should utility be found.

The contacting steps required are of the antibody and polypeptide within a cell that naturally expresses the polypeptide. Yet there is no exemplification whereby a suitable antibody capable of binding and inhibiting any activity of the polypeptide is disclosed and moreover there is no exemplification whereby such an exemplary antibody is recognized as being administered into a cell, contacting the polypeptide and thereby specifically inhibiting the activity of that polypeptide. No proposed relationship

is exemplified for any particular activity in relation to hyperplasia or inflammation or for any second messenger activity in relationship to G-protein mediated signaling.

Receptor structure and function is recognized in the art as differing significantly with respect to the exact ligand, receptor, cell type and with respect to the multiple second messenger pathways that are differentially related in any cell or cell function, see in particular Stadl, Skolnick and Bork above. Moreover, the claims are drawn to various variant amino acids with from at least about 70-90% variability in sequence identity and to various fragments or portions as encompassed via the hybridizing language under particular conditions and to particular fragments. Yet none of these polypeptides or fragments are specifically disclosed or exemplified as relating to any particular activity or cell function.

Moreover with respect to hybridizing and encoding language, the skilled artisan recognizes that nucleic acid alterations may lead to alterations in the amino acids encoded thereby. The skilled artisan also recognizes as exemplified by Choh, PNAS 77(6):3211-14, 1990 that one or more amino acid deletions, insertions or substitutions including truncations results in unpredictable effects in the resultant molecule with respect to biological function, the ability to bind and exhibit immunoreactivity. The specification teaches no structural or functional activities of the polypeptide, fails to teach any residues which may be exchanged while retaining particular structure and activity and fail to teach any specific nucleic acids capable of hybridization with the recited molecules as claimed which encode suitably similar members, especially from the non-coding strand. The skilled artisan recognizes that hybridization is a property dependent upon the structural nucleotides of the hybridizing sequences, the G+C content, the length of the molecules and the temperature and salt hybridization conditions, see for example Jenkins et al., PCR Methods and Applications, S77-82,

1994 which teach differential hybridization of a nucleic acid probe with a single base pair substitution.

Accordingly, the teachings of the specification are not of sufficient particularity or breadth to enable the claimed invention and the skilled artisan cannot readily make and use the claimed invention without further undue experimentation.

9. Claims 32, 34-37, 39-42, 44-47 and 49-59 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a polypeptide sequence consisting of SEQ ID NO:1, contemplated as having a particular activity which may be inhibited by an antibody within a cell, yet the specification fails to describe either via suitable structure or function the polypeptide, its activities or any antibody capable of particularly inhibiting them. Further, the claims as written include polypeptides comprising fragments and homologues, and which vary substantially in length and also in amino acid composition, as encompassed via percent identity recitations, hybridizing and encoding language and also recitation of particular residues. The instant disclosure of a single polypeptide, that of SEQ ID NO:1 with no disclosed specific activity or significance, does not adequately support the scope of a claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”) Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, “requires a precise definition, such as by structure, formula, chemical name, or physical properties,” not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, “an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.” Id at 1170, 25 USPQ2d at 1606.”

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which

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features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polypeptide sequence SEQ ID NO: 1 and no other amino acid sequences that are proposed to possess the same activity.

Receptor function, however, cannot be reliably predicted from protein sequence homology. For example, the Transforming Growth Factor (TGF-beta) Family are particular G-protein coupled receptors, related to instant claims. The particular receptor OP-1 induces metanephrogenesis whereas its closely related TGF-beta family members-BMP-2 and TGF-beta1-have no effect on metanephrogenesis under identical conditions (Vukicevic et al., 1996, PNAS USA 93:9021-9026). Platelet-derived Growth Factor (PDGF) Family VEGF, a member of the PDGF family, is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells while PDGF is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (Tischer et al., U.S. Patent 5,194,596, column 2, line 46 to column 3, line 2). Finally, vertebrate growth hormone of 198 amino acids becomes an antagonist (inhibitor of growth) when a single amino acid is changed (Kopchick et al, U.S. Patent No. 5,350,836). Even 99% homology does allow predictability in this instance.

Given the unpredictability of homology comparisons, and the fact that the specification fails to provide objective evidence of any particular function of SEQ ID NO:1, that the additional sequences are indeed species of the claimed genus, or even function similarly, it cannot be established that a representative number of species have been disclosed to support a genus claim. No activity is set forth for the additional sequences. Thus, the claimed invention lacks adequate written description support.

10. Claims 32, 34-37, 39-42, 44-47 and 49-59 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Review of the application history reveals introduction of the recitation to specific cells including brain, spleen, lung, skeletal muscle, liver and heart, pertinent to instant claims, in particular as recited in claims 32, 37, 42, 47, 52, 58. Support is found at p. 8 for noted expression in brain. However, the Examiner fails to find specific support for noted expression in the other cell types as instantly claimed. Accordingly these recitations constitute new matter absent particular evidence for support.

In addition, Applicants amendment of 2-8-05 recites the step of "contacting the polypeptide with an antibody which binds the polypeptide under conditions that allow the antibody to modulate the activity of the polypeptide, wherein the activity of the polypeptide is modulated in a cell which naturally expresses the polypeptide selected from the group consisting of brain cells, spleen cells, lung cells, skeletal muscle cells, liver cells and heart cells." No support is delineated within the amendment and apparent support is not found. Accordingly, the recitation constitutes new matter absent evidence for support in the specification as originally filed.

Claim Rejections - 35 USC § 102

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11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 32, 34-37, 39-42, 44-47 and 49-59 are rejected under 35 U.S.C. 102(e) as anticipated by Elshourbagy. Each of the independent claims on appeal include within their scope modulating the activity of a polypeptide that comprises the amino acid sequence shown in SEQ ID NO:1 or a method for identifying a compound that modulates the activity of a polypeptide comprising the amino acid sequence shown in SEQ ID NO:1 where the activity of the polypeptide is determined in a kidney cell. As set forth above, Elshourbagy describes modulating the activity of a polypeptide comprising the amino acid sequence shown in SEQ ID. NO:1 or identifying a compound that modulates the activity of that polypeptide. Elshourbagy additionally teaches that the receptors of that invention can be expressed in human embryonic kidney cells. See. Example 1. Thus. Elshourbagy describes an embodiment that is within the scope of

each of the Independent claims on appeal. (In regard to other embodiments within certain of the independent claims, e.g., claim 37 which requires the use of a sequence variant of the amino acid sequence shown in SEQ ID NO:1, we point to column 5, lines 36 - 40 of Elshourbagy that describe polypeptide variants of the amino acid sequence of SEQ ID NO:2 of that reference.)

As to the claims directed to the embodiment where the compound is an antibody, we note that Elshourbagy states that antibodies that are immunospecific for the polypeptide of that invention may be produced, column 9, lines 25 - 31.

As to claims 34, 39, 44 and 49 that require modulating the activity of the polypeptide in a brain cell, we note that many of the conditions taught in Elshourbagy to be treatable by the polypeptide of that invention are neurological disorders. Id., column 12, lines 48 - 62. In view of this disclosure of treating neurological disorders, Elshourbagy fairly describes the use of modulating the activity of the present peptide in brain cells.

In regard to claims 35, 40, 45 and 50 that require that the activity of the polypeptide is modulated in a subject having a disorder associated with hyperplasia or inflammation, we also note that some of the disorders stated by Elshourbagy to be treatable involve inflammation, e.g., asthma and allergies. Id. Thus, Elshourbagy fairly describes the subject matter of these claims.

In regard to claims 36, 41, 46, 51, 53, 55, 57, and 59 wherein the activity to be modulated is a G-protein mediated signal transduction activity, we note that Elshourbagy states that the polypeptides to that invention are believed to be GPCRs,

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column 3, lines 40 - 43, and that GCPRs are involved with signal transduction activity, column 1, lines 34 - 62. claims. Thus, Elshourbagy fairly describes the subject matter of these claims.

Applicants argue in the response of 2-8-05 that the new recitations with respect to antibody and cell types suitably distinguish in that the reference only recognizes the suitability of testis cDNA library.

Applicant's arguments have been fully considered but are not persuasive. Elshourbagy does not appear deficient or limited to testis cDNA cells nor is it deficient as noted in the Boards notation of antibody, inhibition of activity, brain cells etc. Moreover and to further denote with respect to the claim amendments, Elshourbagy teach the suitability of any cell noted to express the receptor, identified in part via antibody reactivity, see in particular column 4, lines 7-8 directed to "naturally occurring polypeptides", column 5, lines 13-16, "obtained from natural sources", particularly "obtained from a subject's cells, such as from blood, saliva, tissue biopsy or autopsy material," column 7-8 paragraph spanning. Also, assessment of expression levels of polypeptide via antibody binding analysis as in "radioimmunoassays, competitive binding assays, Western blot analysis and ELISA assays," is taught at column 8, lines 39-44. In particular, assays for identifying antagonists or agonists of function are taught at column 10-13, in particular via "measuring the binding of a candidate compound to the polypeptide, or to cells or membranes bearing the polypeptide," column 10, lines 65-67, "compounds may be identified from a variety of sources, for example, cells," column 10, lines 56-57, "One screening technique includes the use of cells which express the

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receptor of this invention", column 11, lines 27-28, specific guidance to such analysis via antibody binding is noted for example at column 11, lines 50-column 12, line 10, particularly column 11, lines 51-61, "screening method for detecting the effect of added compounds on the production of mRNA and polypeptide in cells. For example, an ELISA assay may be constructed for measuring secreted or cell associated levels of polypeptide using monoclonal and polyclonal antibodies by standard methods known in the art. This can be used to discover agents which may inhibit or enhance the production of polypeptide (also called antagonist or agonist respectively) from suitably manipulated cells or tissues", and further "a cell membrane expressing a polypeptide of the present invention or an antibody to a polypeptide of the present invention," column 12, lines 27-30. As previously remarked in the Boards rejection, the suitable guidance to brain and kidney cells is further noted via the referral to treatment of such neurodegenerative conditions in neurons and to experimentation with kidney cells, but also is Elshourbagy on point to the referral of "asthma" with the respect to the recitation of lung cells, "acute heart failure", with respect to heart cells, dyskinesias with respect to "skeletal muscles," and also, the aforementioned analysis of cells suitably expressing, over-expressing or under-expressing the polypeptide. Accordingly the suitability of the requisite cells of expression via either DNA or peptide analysis are clearly encompassed and suitably enabled to anticipate those cells expressing the polypeptide. Similar to kidney and brain cells being suitably identified and enabled, so to are the suitable cells of expression noted. Therefore rejection is maintained as articulated via the Board and as set forth herein.

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13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

Sharon L. Turner, Ph.D.
June 13, 2005


SHARON TURNER, PH.D.
PRIMARY EXAMINER
6-13-05